E-shunt and a little more

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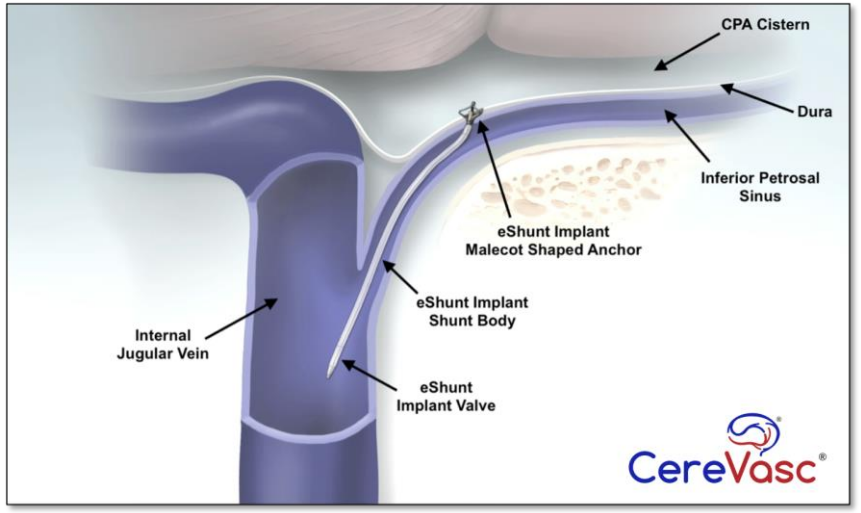
E-Shunt

The new eShunt (CereVasc) presents a groundbreaking, minimally invasive endovenous approach that mimics the function of arachnoid granulations and redirects CSF from the subarachnoid space to venous sinuses without open surgical intervention



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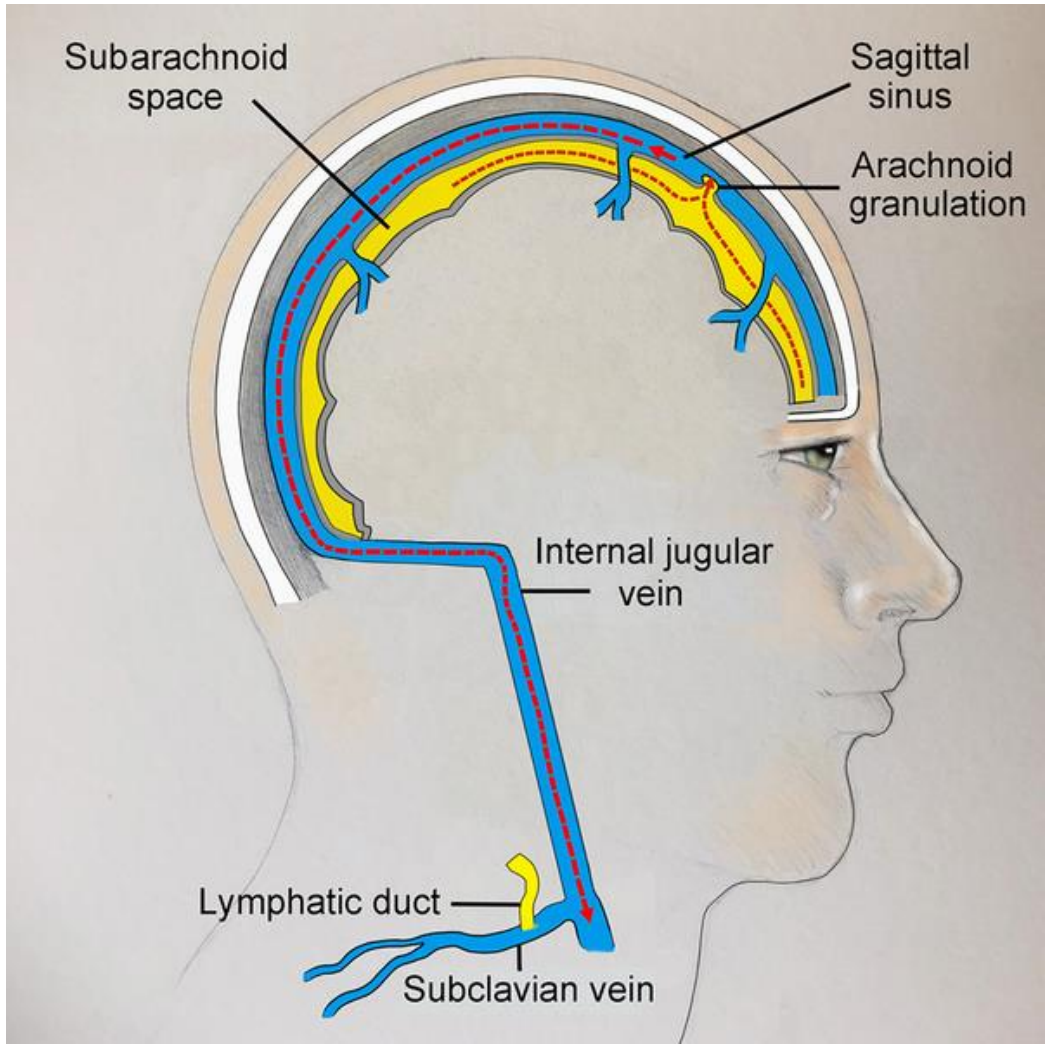
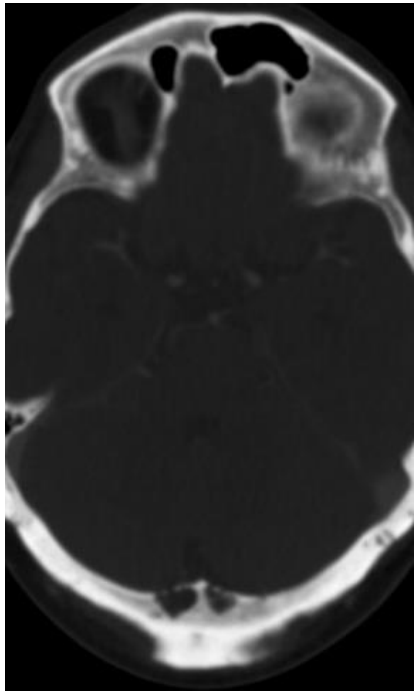
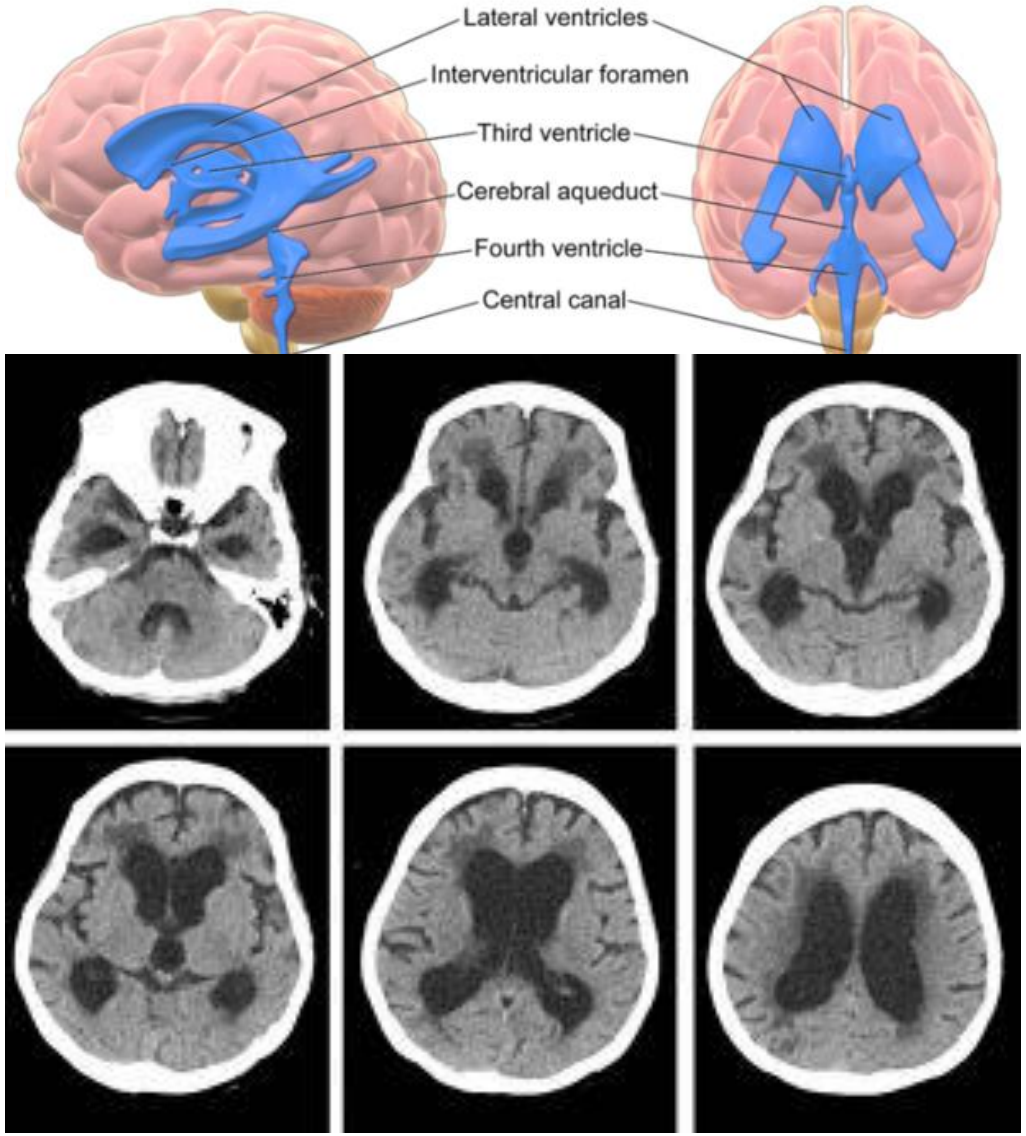


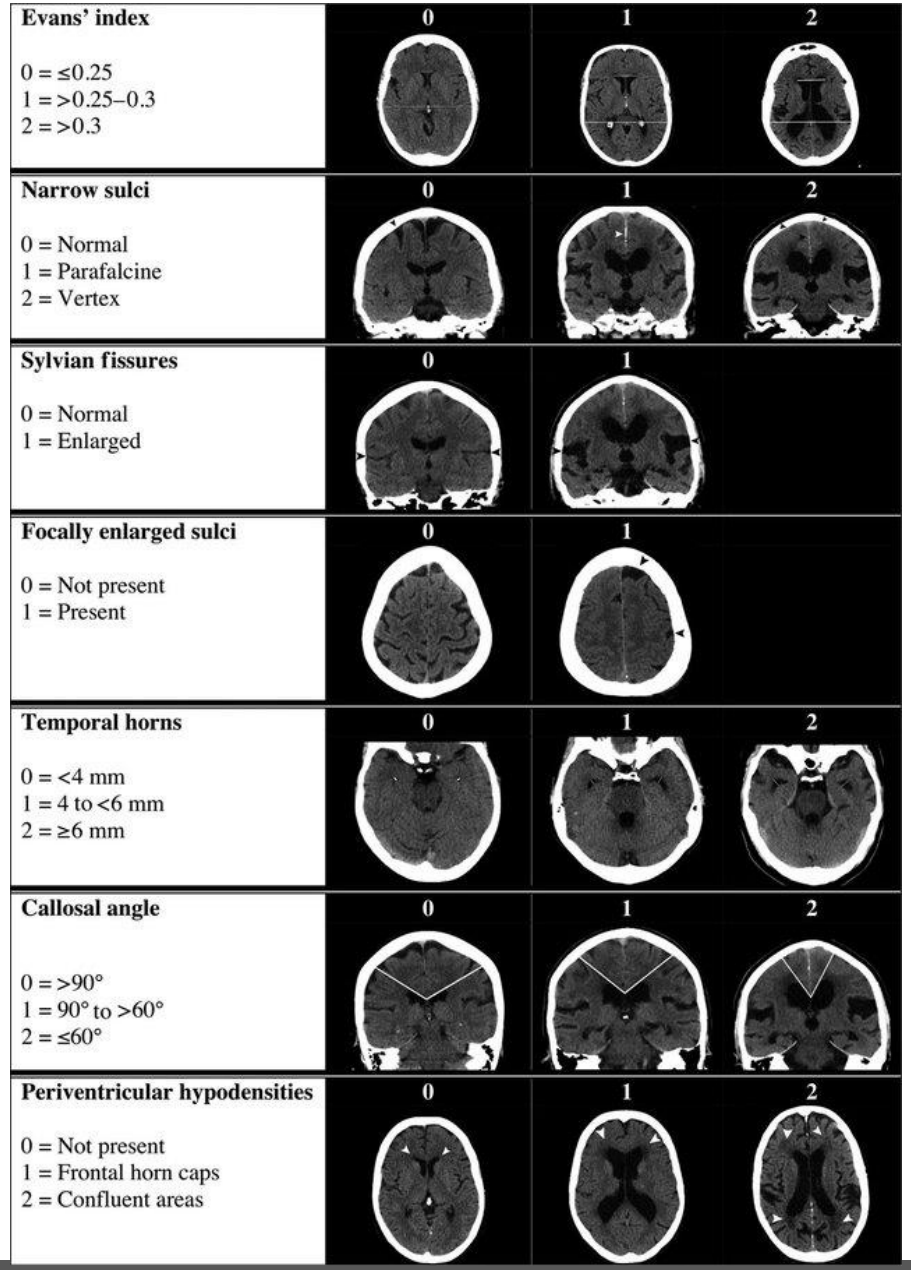
Arachnoid Granulations



Pessa JE. Identification of a novel path for cerebrospinal fluid (CSF) drainage of the human brain. PLoS One. 2023 May 4;18(5):e0285269



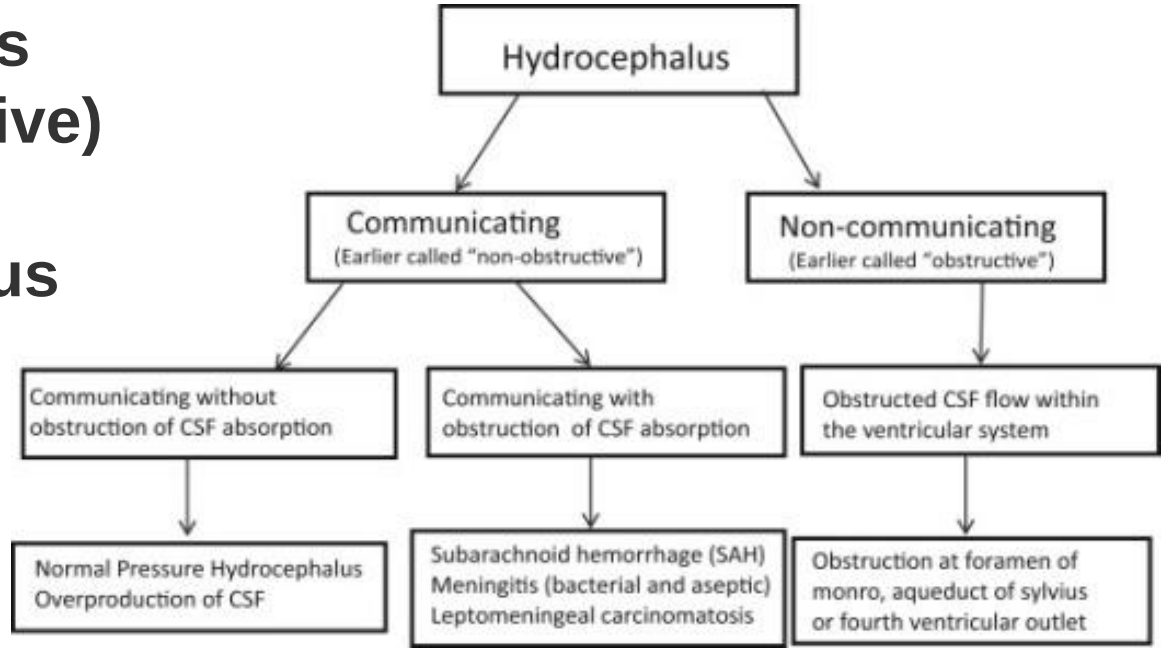
Hydrocephalus is characterized by an abnormal buildup of cerebrospinal fluid (CSF) within the brain, causing the ventricles (cavities within the brain) to widen and potentially increasing pressure on the brain tissue.



Kockum K, Lilja-Lund O, Larsson EM, Rosell M, Söderström L, Virhammar J, Laurell K. The idiopathic normal-pressure hydrocephalus Radscale: a radiological scale for structured evaluation. Eur J Neurol. 2018 Mar;25(3):569-576.

Types of Hydrocephalus

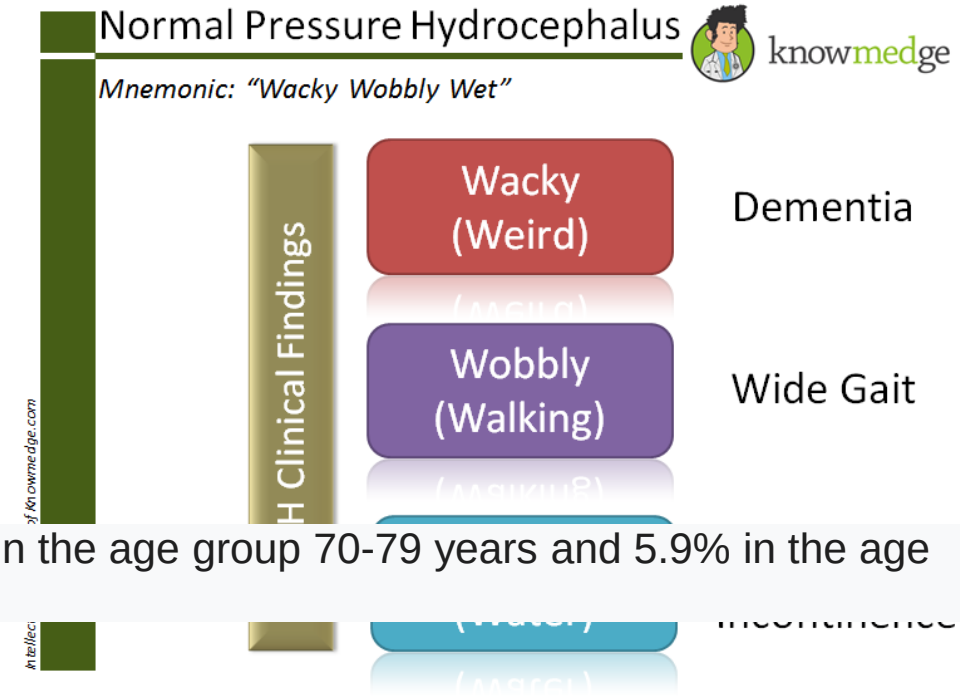
1. Communicating Hydrocephalus
2. Non-communicating (Obstructive) Hydrocephalus
3. Normal Pressure Hydrocephalus (NPH)



Rekate, HL, Raybaud, Charles. Pediatric Hydrocephalus. Part 1: Classification of Hydrocephalus, Radiology of Hydrocephalus. From Morphology to Hydrodynamics and Pathogenesis. SpringerLink. 2018. pages 390-449, 480-482

Normal pressure hydrocephalus (NPH)

Normal pressure hydrocephalus (NPH) is a condition where there is an abnormal buildup of cerebrospinal fluid (CSF) in the brain, causing the ventricles (cavities in the brain) to enlarge. This enlarged space leads to compression of brain tissue, resulting in neurological symptoms. Despite the excess fluid, the pressure measured during a spinal tap is typically normal, hence the name "normal pressure hydrocephalus".

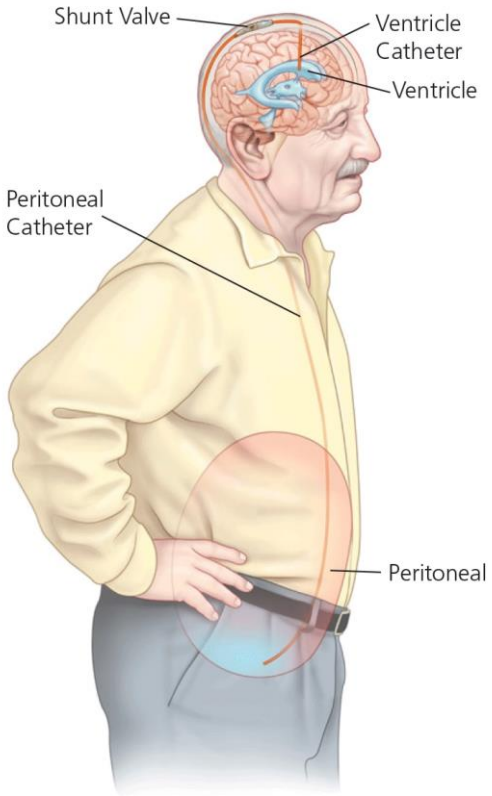


The prevalence of NPH increases with age and is 0.2% in the age group 70-79 years and 5.9% in the age group >80 years

Jaraj D, Rabiei K, Wikkelso C et al. Prevalence of idiopathic normal-pressure hydrocephalus. Neurology 2014;82:1449-54

Ventriculoperitoneal (VP) shunt

Current standard treatment of hydrocephalus remains ventriculoperitoneal (VP) shunt surgery first introduced over 60 years ago, requiring multiple scalp, neck, and abdominal incisions, a burr hole, and catheter traversing cortex and white matter.



Lylyk P, Lylyk I, Bleise C, et al. J NeuroIntervent Surg 2022;14:495–499.

Ventriculoperitoneal (VP) shunt - problems

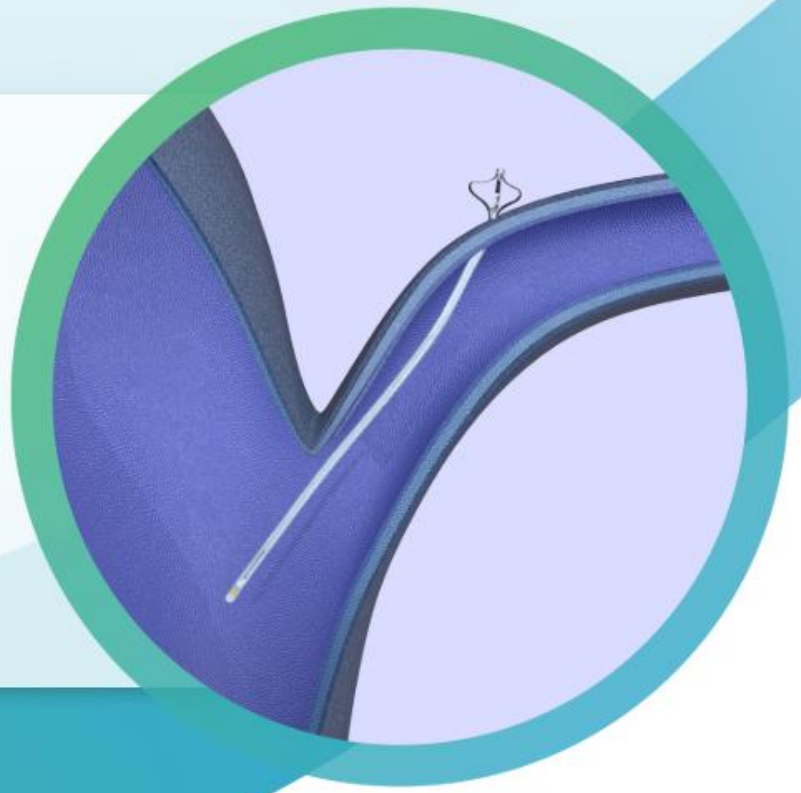
- The VP shunt has remained largely unchanged except for development of externally adjustable valves and modifications to mitigate siphoning
- A risk of surgical infection of around 10%
- High overall VP shunt failure rates, estimated to be between 21% and 42% by the first year following placement

Kofoed Månsson P, Johansson S, Ziebell M, et al. Forty years of shunt surgery at Rigshospitalet, Denmark: a retrospective study comparing past and present rates and causes of revision and infection. BMJ Open 2017;7:e013389.
Merkler AE, Ch'ang J, Parker WE, et al. The rate of complications after ventriculoperitoneal shunt surgery. World Neurosurg 2017;98:654–8.
Reddy GK, Bollam P, Shi R, et al. Management of adult hydrocephalus with ventriculoperitoneal shunts: long-term single-institution experience. Neurosurgery 2011;69:774–81

COMPARING THE eShunt® SYSTEM AND VP SHUNTS

The STRIDE clinical trial is evaluating the safety and efficacy of the investigational eShunt System—an endovascular approach to normal pressure hydrocephalus (NPH) treatment

Caution: *The eShunt System is an investigational device. Limited by United States law to investigational use only. The safety and effectiveness of the eShunt System have not been established.*



Traditional VP Shunts	The Endovascular eShunt System
Studies have shown VP shunts to be effective, despite the high complication rates reported during and after surgery[1]	A new, investigational device with the potential to reduce patient and caregiver burden due to challenges seen with VP shunts* *Refer to the eShunt® System Instructions for Use for list of potential risks.
Requires **invasive, open brain surgery**[2]	Uses a **minimally invasive, endovascular** approach with femoral venous access
Drains excess CSF by **routing it to another location** in the body to be absorbed[2]	Designed to drain excess CSF in the brain by **mimicking the body's natural drainage process**

The FDA recently designated the eShunt System as a Breakthrough Device because of its potential to provide improved treatment for NPH[3†]

FDA, Food and Drug Administration.
†Breakthrough designation does not imply approval or guaranteed safety and effectiveness.

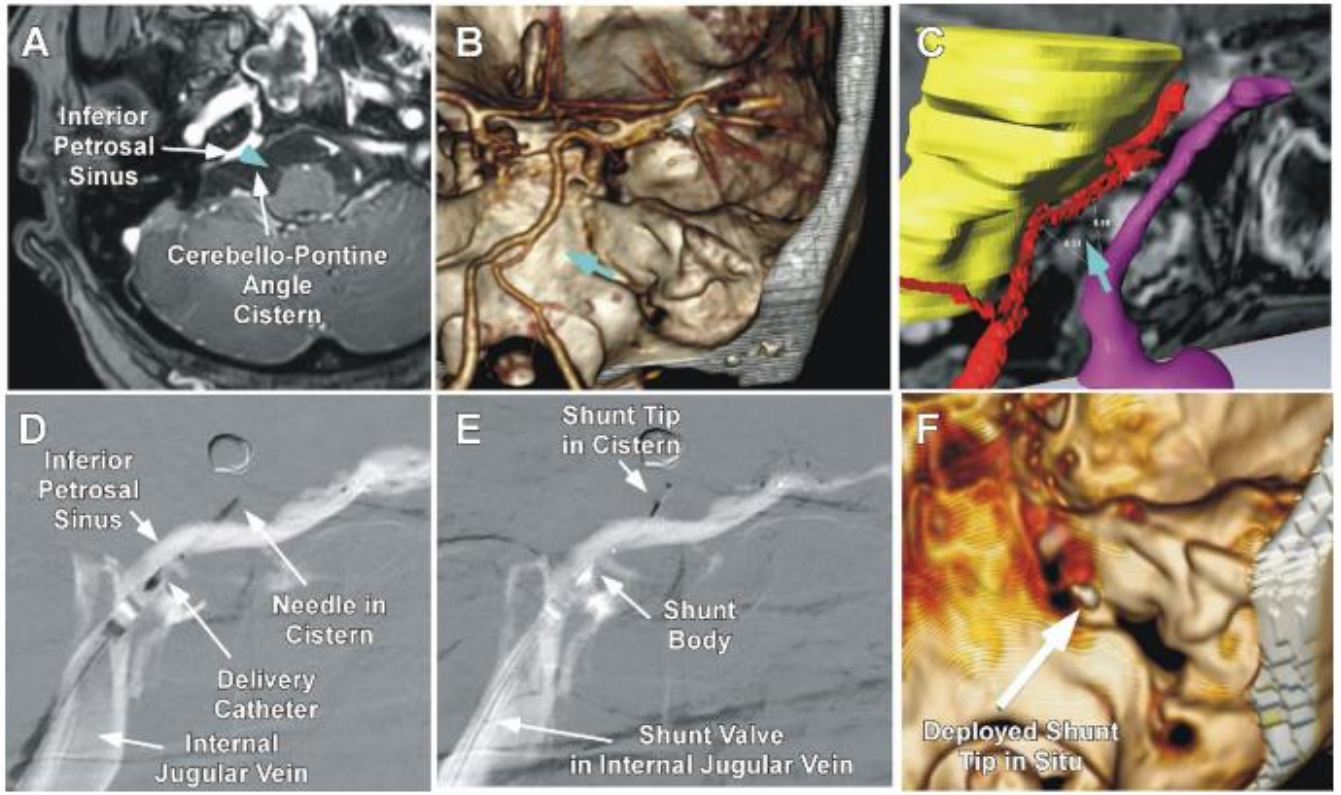


Figure 2 (A) T1-Weighted axial gadolinium-enhanced MRI scan highlights the inferior petrosal sinus (IPS) and adjacent cerebellopontine angle (CPA) cistern (arrow showing intended transdural device placement). (B) Three-dimensional rendering of computed tomographic angiography with arrow highlighting intended transdural trajectory for deployment. (C) Segmentation from T1-gadolinium- enhanced MRI scan highlights the IPS (purple), vertebral and posterior inferior cerebellar artery (red) and their >6 mm distance away from the intended trajectory (arrow) for transdural egress of eShunt. (D) Intraprocedural IPS roadmap showing successful dural penetration with delivery catheter needle into the CPA cistern. (E) Successful deployment of the eShunt with its tip in the CPA cistern, its body in the IPS, and its valved tip draining into the internal jugular vein. (F) Postprocedural reconstruction of computed tomographic acquisition confirming stable position of eShunt malecot tip at intended target site.

3D MRI and cone-beam CT are used for planning and image guidance

Heilman CB, Basil GW, Beneduce BM, et al. J NeuroIntervent Surg 2019;11:598–602.

Study Design

The STRIDE clinical trial is the largest, randomized, controlled trial in the treatment of NPH comparing the new, investigational endovascular eShunt® System vs the standard of care VP shunt.

Estimated Enrollment

Total of 200 treated participants

1:1 Randomized Study Groups

eShunt® System Group: 100 patients to receive endovascular treatment with the eShunt® System

- 1 overnight hospital stay required

VP Shunt Group: 100 patients to receive traditional VP shunt procedure/device

- Length of hospital stay to be determined by treating physician

Study Duration

1 year of follow-up post procedure with up to 5 years of focused care

STRIDE Eligibility Requirements At a Glance

History

- Aged ≥60 years
- History or evidence of gait impairment for ≥3 months
- Clinical presentation consistent with NPH, including ≥2 of the 3 key symptoms

Testing

- Results from additional testing, including lumbar drain and MoCA
- Confirmation of anatomy suitable for the eShunt procedure with imaging (CT and MRI)

Consent

- Patient or caregiver is able and willing to provide written informed consent, attend all scheduled visits, and comply with study procedures

Key exclusion criteria

- Inability to walk 33 feet (10 meters) with or without an assistive device
- Diagnosed with obstructive hydrocephalus
- Prior or existing shunts, endoscopic third ventriculostomy, or any previous surgical intervention for hydrocephalus

VIEW FULL INCLUSION AND EXCLUSION CRITERIA

Primary Efficacy Endpoint

Improvement in gait impairment at 6 months compared to baseline.

- Improvement defined as a reduction in time to complete the TUG test, which requires patients to stand up, walk 10 feet, turn around, walk 10 feet, and sit back down

Primary Safety Endpoint

Comparison of the total number of adverse events observed within the first 6 months following treatment.

P-031 **ONE-YEAR SAFETY OF THE ESHUNT® IMPLANT USED IN THE TREATMENT OF COMMUNICATING HYDROCEPHALUS**

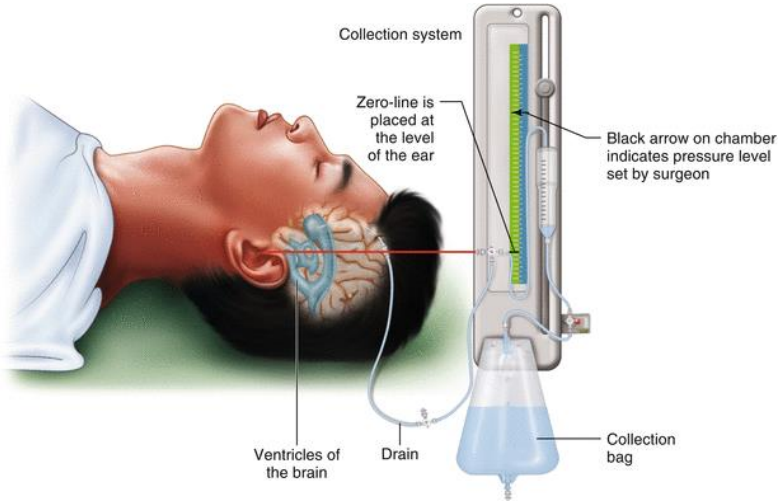
[1]P Lylyk, [2]C Matouk, [3]A Siddiqui, [4]H Riina, [1]I Lylyk, [1]C Bleise, [1]E Scrivano, [1]P Lylyk, [2]J Antonios, [5]B Beneduce, [6]E Levy, [7]C Heilman, [7]A Malek*. *[1]Neurosurgery, ENERI, Clinica La Sagrada Familia, Buenos Aires, Argentina; [2]Neurosurgery, Yale New Haven Hospital, New Haven, CT; [3]Neurosurgery, University at Buffalo, Buffalo, NY; [4]Neurosurgery, NYU Langone, New York, NY; [5]CereVasc, Inc., Charlestown, MA; [6]Neurosurgery, University at Buffalo, Williamsville, NY; [7]Neurosurgery, Tufts Medical Center, Boston, MA*

Longterm safety

- Through one-year follow-up in 14 patients no observations of radiographic or symptomatic overdrainage or subdural hygromas were detected.
- There were no instances of procedural or delayed subarachnoid, intraparenchymal or subdural hemorrhage.
- Cross-sectional imaging immediately postoperatively compared to one-year confirmed stability of the Implant without antegrade or retrograde migration.
- mRS scores were either stable or improved at one-year relative to baseline

Intractable Hydrocephalus Following Aneurysmal Subarachnoid Hemorrhage

- Nine patients (6 female; mean 62.6+/−21.4 years) underwent successful transfemoral transvenous Implant placement at a mean 28.7 days following initial aSAH.
- All patients achieved the primary endpoint, enabling EVD removal 36–48 hours following Implant placement.
- No cases of delayed hemorrhage occurred in the follow-up period.
- Mean ICP rapidly decreased from pre-procedural clamping pressure of 34.4 to 10.8 cmH2O within 1 hour (p<0.0001) and remained within the normal range at 10.9 cmH2O (p<0.0001) 36 hours post-Implant placement.



Management of Intractable Hydrocephalus Following Aneurysmal Subarachnoid Hemorrhage with the eShunt® System Endovascular CSF Shunt (S16.004) Pedro Lylyk, Ivan lylyk, Carlos Bleise, Esteban Scrivano, Pedro N. Lylyk, Brandon Beneduce, Carl Heilman, and Adel Malek
Neurology; April 9, 2024 issue

Chronic headaches and middle meningeal artery

Endovascluar therapy observations

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Middle Meningeal Artery (MMA)

- MMA main feeder of the dura
- Ipsilateral dilated during migraines

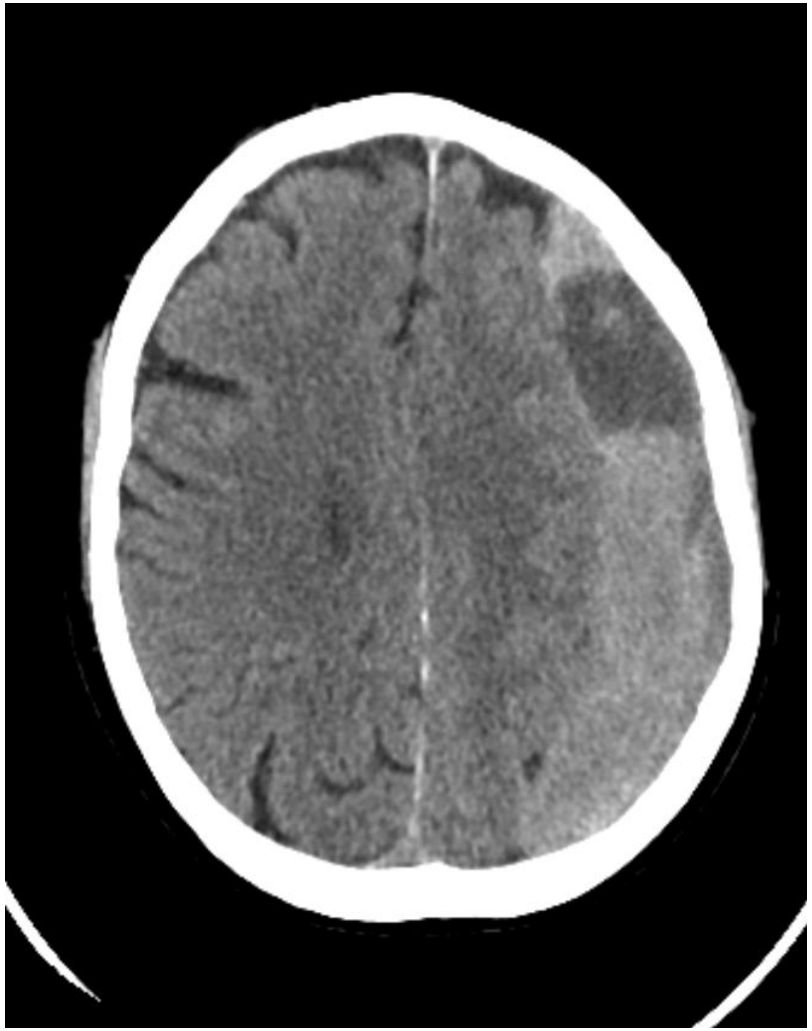
Catapano JS, et al. JNIS 2022;14:301-303
Fiorella D, et al. JNIS 2023
Entezema P, et al. Headache 2019

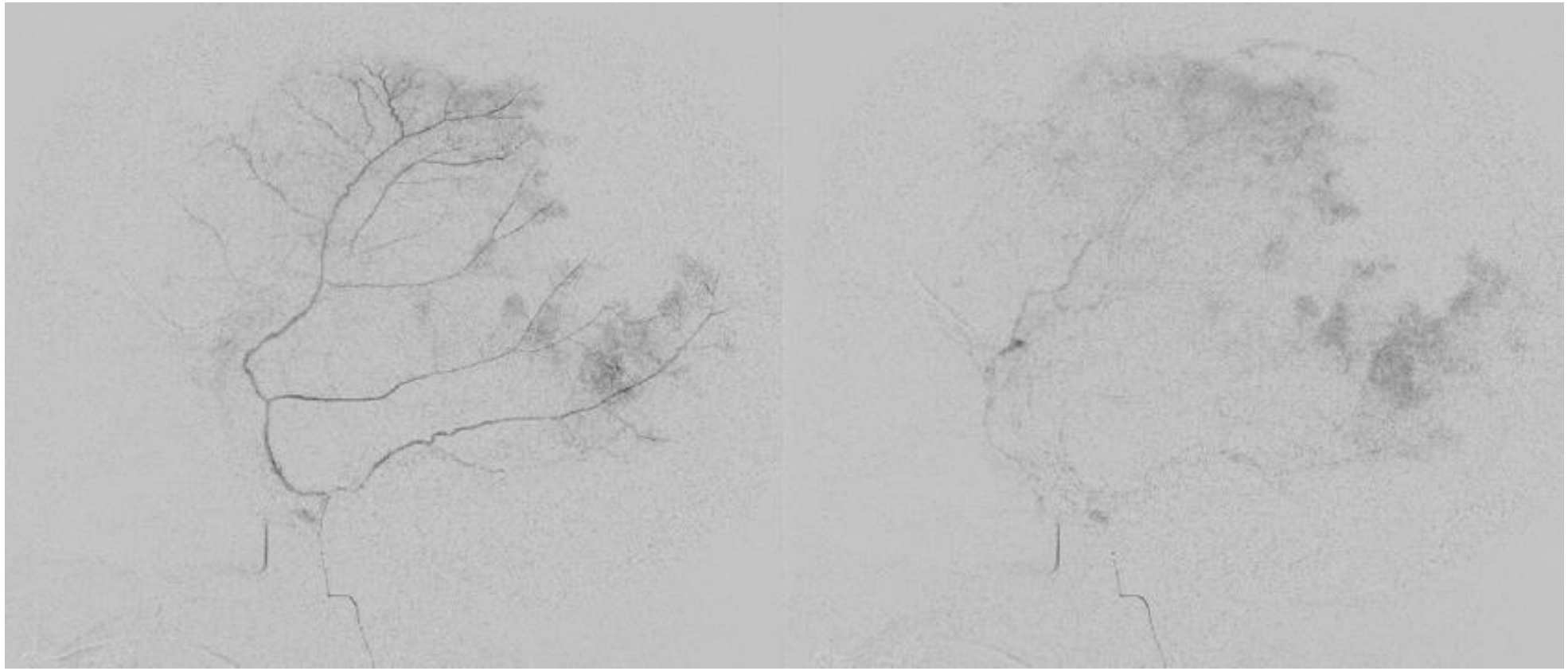
MMA and migraine

- Vasodilation may release vasoactive molecules leading to activation of dural nociceptors and additional release of inflammatory cytokine
- A positive feedback cycle may be induced

Buzzi et al. Cephalalgia 1995; 15: 277-80
Fricke et al. Microsc. Res Tech 2001; 53:96-100

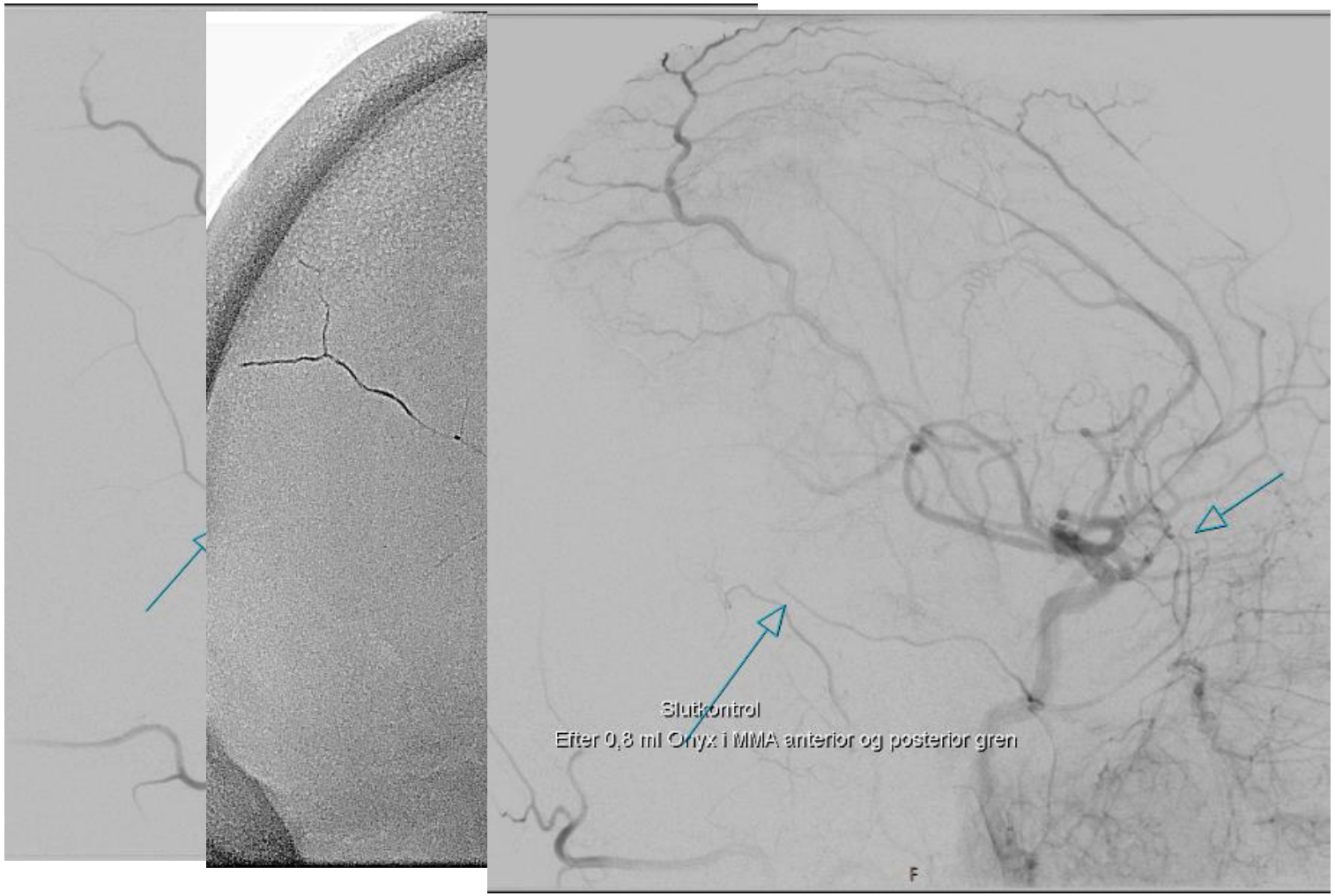

X1
X1 Distance: 12.36 mm
F





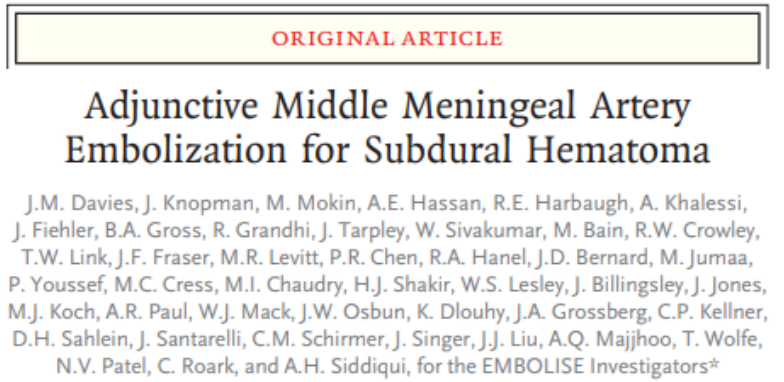
https://neuroangio.org/sample-page/neuroangio-topics/subdural-hematoma-embolization/

eMMA for cSDH



eMMA for cSDH

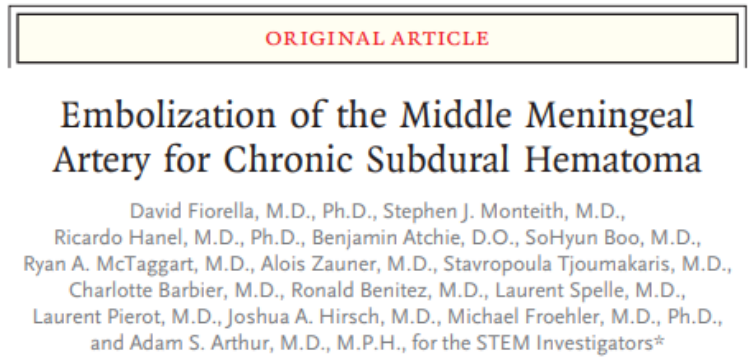
- Three RCT published in NEJM
- Lower risk of cSDH recurrence leading to reoperation
- eMMA a low risk treatment



ORIGINAL ARTICLE

Adjunctive Middle Meningeal Artery Embolization for Subdural Hematoma

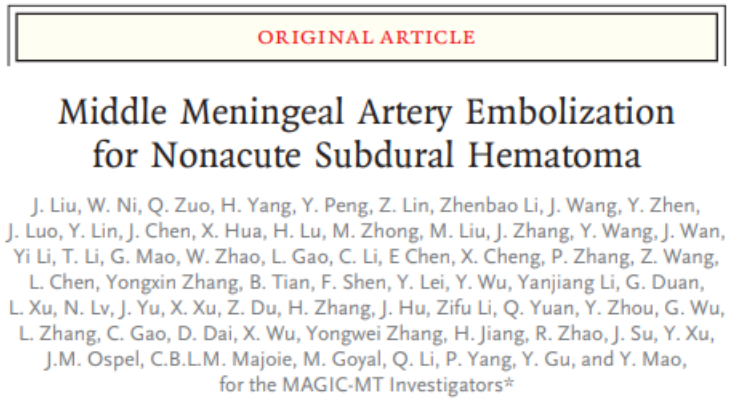
J.M. Davies, J. Knopman, M. Mokin, A.E. Hassan, R.E. Harbaugh, A. Khalessi, J. Fiehler, B.A. Gross, R. Grandhi, J. Tarpley, W. Sivakumar, M. Bain, R.W. Crowley, T.W. Link, J.F. Fraser, M.R. Levitt, P.R. Chen, R.A. Hanel, J.D. Bernard, M. Jumaa, P. Youssef, M.C. Cress, M.I. Chaudry, H.J. Shakir, W.S. Lesley, J. Billingsley, J. Jones, M.J. Koch, A.R. Paul, W.J. Mack, J.W. Osbun, K. Dlouhy, J.A. Grossberg, C.P. Kellner, D.H. Sahlein, J. Santarelli, C.M. Schirmer, J. Singer, J.J. Liu, A.Q. Majjhoo, T. Wolfe, N.V. Patel, C. Roark, and A.H. Siddiqui, for the EMBOLISE Investigators*



ORIGINAL ARTICLE

Embolization of the Middle Meningeal Artery for Chronic Subdural Hematoma

David Fiorella, M.D., Ph.D., Stephen J. Monteith, M.D., Ricardo Hanel, M.D., Ph.D., Benjamin Atchie, D.O., SoHyun Boo, M.D., Ryan A. McTaggart, M.D., Alois Zauner, M.D., Stavropoula Tjoumakaris, M.D., Charlotte Barbier, M.D., Ronald Benitez, M.D., Laurent Spelle, M.D., Laurent Pierot, M.D., Joshua A. Hirsch, M.D., Michael Froehler, M.D., Ph.D., and Adam S. Arthur, M.D., M.P.H., for the STEM Investigators*



ORIGINAL ARTICLE

Middle Meningeal Artery Embolization for Nonacute Subdural Hematoma

J. Liu, W. Ni, Q. Zuo, H. Yang, Y. Peng, Z. Lin, Zhenbao Li, J. Wang, Y. Zhen, J. Luo, Y. Lin, J. Chen, X. Hua, H. Lu, M. Zhong, M. Liu, J. Zhang, Y. Wang, J. Wan, Yi Li, T. Li, G. Mao, W. Zhao, L. Gao, C. Li, E Chen, X. Cheng, P. Zhang, Z. Wang, L. Chen, Yongxin Zhang, B. Tian, F. Shen, Y. Lei, Y. Wu, Yanjiang Li, G. Duan, L. Xu, N. Lv, J. Yu, X. Xu, Z. Du, H. Zhang, J. Hu, Zifu Li, Q. Yuan, Y. Zhou, G. Wu, L. Zhang, C. Gao, D. Dai, X. Wu, Yongwei Zhang, H. Jiang, R. Zhao, J. Su, Y. Xu, J.M. Ospel, C.B.L.M. Majoie, M. Goyal, Q. Li, P. Yang, Y. Gu, and Y. Mao, for the MAGIC-MT Investigators*

Chronic headaches and middle meningeal artery embolization

- 76 patients underwent eMMA for cSDH
- 46 patient contacted for telephone follow-up
- 25 reported with headaches before eMMA
- 9 chronic headaches at least 2 years before the cSDH

Capitano et al. J Neurointervention Surg 2022;14:313-303

Chronic headaches and middle meningeal artery embolization

- 25/46 patients reported headaches before eMMA (including 9 with chronic headches)
- 7/36 patients reported headaches on follow-up (including 2 with chronic heaches)

Capitano et al. J Neurointervention Surg 2022;14:313-303

Table 2 Patient characteristic and outcome data of the severe chronic headache group

Case	Age, decade	Pre-embolization medications for headaches	Bilateral embolization	Headaches after embolization	HIT-6 score		Telephone follow-up, days*
					Pre-embolization	Post-embolization	
1	50s	Acetaminophen	No	Resolved	61	36	568
2	40s	Ibuprofen	No	Worse, requires more medication	60	63	850
3	70s	None	Yes	Resolved	57	36	621
4	60s	Triptan	No	Improved, requires less medication	67	44	527
5	70s	Ibuprofen	Yes	Resolved	54	36	429
6	70s	None	Yes	Resolved	60	36	405
7	40s	Aspirin	Yes	Resolved	72	36	338
8	70s	Ibuprofen	Yes	Resolved	70	36	304
9	60s	None	Yes	Resolved	74	36	360

*Days after embolization.
HIT-6, Headache Impact Test.

Catapano JS, *et al*. *J NeuroIntervent Surg* 2022;**14**:301–303. doi:10.1136/neurintsurg-2021-017602

Effect of intra-arterial injection of lidocaine and methyl-prednisolone into middle meningeal artery on intractabel headaches - case reports

- 66 y/o male migraine headaches for 1 day – no response to normal treatment and headache intensity VAS 10
- After infusion the patient reported VAS 8 and 24h later VAS 5

- 33 y/o female 4 days heachaches, history of ICH – no response to morphine, sumatriptan or hydrocodone-acetaminophen. Intensity 7
- After infusion the patient reported VAS 4 and mild headache at 16h post-procedure

Qureshi et al. JVIN 2014

Effect of intra-arterial injection of lidocaine and methyl-prednisolone into middle meningeal artery on intractabel headaches - case reports

- Lidocaine injection into MMA is expected to result in temporary anaesthesia of the nerves supplying the dura
- Complications – Transient visual loss and temporary facial nerve paresis

Qureshi et al. JVIN 2014

Use of lidocaine to treat migraine

- The use of IV lidocaine for the treatment of pain is believed to be primarily related to its ability to block voltage gated sodium channels, a synergetic effect with opioids.

Fiorella et al. J Neurointervention Surg Month 2023 vol 0

Procedure of lidocaine injection in the MMA

- Local anestehsia
- Radial/femoral access
- SIM2 cat. External carotid – diagnostic of the MMA anatomy
- Microcat. 0.017/0.021 main trunk of MMA
- 50 mg of cardiac preservative-free lidocaine (1mg/1ml Saline) infused slowly over 5-10 min
- Neurologic status – ocular or facial nerve symptoms can be monitored throughout the infusion

Fiorella et al. J Neurointervention Surg Month 2023 vol 0

Refractory migraines and headaches

- Current prophylactic treatment not sufficient
- Emergent medications with opioids or barbiturates may cause abuse, misuse, or dependence.

Endovascular MMA treatment

- MMA treatment may reduce healthcare cost
- Improve patient quality of life
- Reduction of opioid and barbiturate misuse and dependence

First symposium on endovascular treatment of headache in Copenhagen

30. October 2025

SAVE THE DATE